## SECTION II. 510(K) SUMMARY

### *A. Device Name*

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| Proprietary Name: | Heartrail™ III Guiding Catheter |
| Classification Name: | Diagnostic Intravascular Catheter |
| Common Name: | Guiding Catheter |

### *B. Intended Use*

The Heartrail III Guiding Catheter is intended for cardiac and vascular procedures. It is designed to deliver radiopaque media, guide wires, catheters, and therapeutic agents to selected sites in the vascular system. The different shapes are designed to selectively engage arteries from access sites such as the radial artery.

### *C. Device Description*

The Heartrail III Guiding Catheter is a three-layer construction comprised of a stainless steel mesh sandwiched between a layer of polytetrafluoroethylene and a layer of polyester elastomer. The polyester elastomer contains tungsten for visibility and contrast under fluoroscopy in the distal portion of the catheter. The Catheter has a "soft-tip" whose purpose is to minimize trauma to the vessel wall. The soft-tip is a flexible, supple polyester elastomer containing tungsten. This tip is permanently welded to the catheter shaft. Depending on the product code, the tip is either straight or curved into a specific shape.

### *D. Principle Of Operation / Technology*

The Heartrail III Guiding Catheter is operated manually or by a manual process.

### *E. Design / Materials*

The Heartrail III Guiding Catheter in this submission uses similar materials as the predicate devices. Differences in materials between the devices do not raise any new issues of safety and effectiveness.

## *F. Specifications*

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| Available Sizes | 6 Fr. |
| Catheter Length | 100 cm |
| Maximum Injection Pressure | 700 psi. |

## *G. Performance*

The performance of the Heartrail III Guiding Catheter is substantially equivalent to the performance of the predicate devices. The equivalence was shown through bench testing.

## *H. Additional Safety Information*

Manufacturing controls include visual, functional, dimensional and sterility tests.

Blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing".

The catheter is classified as Externally Communicating Devices, Circulating Blood, limited Contact (≤24 hrs). Results of the testing demonstrate that the blood contacting materials are biocompatible.

Sterilization conditions have been validated in accordance with ANSI/AAMI/ISO 11135-1, Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of sterilization process for medical devices. The device is sterilized to a SAL of $10^{-6}$.

## *H. Substantial Equivalence*

The Heartrail III Guiding Catheter submitted in this 510(k) is substantially equivalent in intended use, design, principle of operation / technology, and materials to the Radifocus® Optitorque™ Angiographic Catheter K082736. It was also found to be substantially equivalent[2] in intended use, design, principle of operation / technology, materials, and performance to the Boston Scientific Mach 1 Catheter which was cleared under K981788. Differences between the devices do not raise any issues of safety or effectiveness.

## *I. Submitter Information*

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|---|---|
| Prepared By: | Mr. Mark Unterreiner<br>Sr. Regulatory Affairs Specialist |
| Prepared For: | Terumo Medical Corporation<br>950 Elkton Blvd.<br>Elkton, MD 21921<br>Phone: (410) 392-7213<br>Fax: (410) 398-6079<br>Email: mark.unterreiner@terumomedical.com |
| Date Prepared: | July 29, 2009 |

[2] A statement of substantially equivalence to another product is required by 21CFR807.87, and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent, and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the Commissioner of the FDA has stated, "...a determination of substantial equivalence under the federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatever on the resolution of patent infringement suits" 42 Fed. Reg. 42,520, et seq. (1977)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 11 2009

Terumo Medical Corporation
c/o Mr. Mark Job
1394 25th St. NW
Buffalo, MN 55313

Re: K092372
Trade/Device Name: Heartrail™ III Guiding Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: August 27, 2009
Received: August 28, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K092372

Device Name: Heartrail™ III Guiding Catheter

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kuhn

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092372